Related Application

This application is a §371 national stage application of PCT/US00/13118, which claims priority to U.S. provisional application serial nos. 60/134,331 filed May 14, 1999 and 60/134,572 filed May 17, 1999.

Paragraph beginning at line 3 of page 9 has been amended as follows:

The implant device is particularly useful in treating ischemic tissue such as that often occurs in a myocardium of the heart. As shown in FIG. 1 the implant device may be inserted into the tissue 6, such as that of the myocardium, through the epicardial surface 20 at entry site 24 such that the device extends the majority of the thickness of the myocardium towards endocardial surface 22. Also, the device is fully implanted within the tissue such that the proximal laterally extending arm 16 is submerged within the tissue.

Paragraph beginning at line 9 of page 9 has been amended as follows:

FIG. 2 shows an end view of the device 2 and in particular the laterally extending arm 16, which is configured to prevent migration of the device. As is seen in FIG. 2 the arm extends from the most proximal coil 18 in a tangential direction from the round coil. The arm 16 then curves slightly in the direction of the curvature of the coil. Preferably the lateral extent of the arm beyond the outside diameter of the device is approximately 1 - 3 mm. Generally the diameter of the body 8 of the coil is preferably on the order of 2 - 3 mm. The arm serves to provide increased surface area engaged with the tissue to prevent migration in an axial direction through the tissue. Furthermore, the implantation of the arm into the tissue causes it to prevent rotation of the device so that the device cannot back out of its tissue implant site.

Paragraph beginning at line 1 of page 10 has been amended as follows:

FIG. 5 shows another preferred embodiment of the implant device. A semi-tapered coil spring implant device 40 may also provide adequate anchoring in dynamic

tissue such as the tissue of the myocardium while meeting the objectives of the invention. The implant device 40 comprises a helical coil spring 42 having a proximal portion 44 and a distal portion 46. The individual coils 48 of the spring 42 increase in diameter through the proximal portion 44. Each coil increases in size in the proximal direction. However, the coils of the distal portion 46 are a constant diameter that is somewhat smaller than the diameter of the coils of the proximal portion. The most proximal coil 50 does not extend laterally outward as with the previous embodiment, rather it terminates in its position as part of the helical coil arrangement. The proximal end of the coil may be formed to have a bulbous shape 52 to further resist penetration of the tissue after the device has been implanted. As with the previous embodiment, the tissue tends to herniate at points 26 along the length of the implant. In experiments, the implant device 40 has shown to resist migration and rotation by virtue of the partial increase in taper at the proximal portion 44 of the device. This configuration may also serve to resist migration due to the enhanced flexibility of the proximal coils by virtue of their increased diameter. Increasing the overall diameter of the proximal coils (while maintaining the same filament thickness) serves to increase the flexibility of those coils.

Paragraph beginning at line 19 of page 10 has been amended as follows:

FIG. 6 shows an end view of the implant device 40 having a partial taper at the proximal portion 44. As with the first embodiment, the most proximal coil 50 is submerged within the tissue 6 when the device is implanted. The submersion of the most proximal coil provides the advantages detailed above and additionally avoids placing a section of the coil across the transition between the tissue and tissue surface, which may tend to move differently placing an increased stress on the device and possibly leading to premature failure. FIG. 7 shows a variation of the preferred embodiments discussed above wherein the increasing taper is present throughout the length of the device 80 such that each coil increases in diameter in a direction from the distal end 82 to the proximal end 84. The full taper embodiment 80 is believed to offer the same benefits as described in connection with the device shown in FIG. 5. In the

above described tapered embodiments the smaller distal coils 46 may define a diameter on the order of approximately 2.2 millimeters measured to the outside diameter of the coils and the larger diameter, maximum extent of the taper may be on the order of 4.5 to 5 millimeters. The devices are preferably on the order of 7 - 8 mm in length.

Paragraph beginning at line 3 of page 11 has been amended as follows:

FIG. 8 shows an alternate embodiment of an implant device having an anchoring mechanism. The coil device has an interior 98, which is defined by the individual turns 120 of the coil. The helical coil 96 defines a frame, which holds back surrounding tissue so that blood may pool in the interior chamber, coagulate and become fibrin. Spaces 122 between individual turns of the coil permit communication between the interior chamber 98, where fibrin will grow and the blood and tissue that surround the device. Open ends 124 also permit communication between the interior chamber 98 and surrounding tissue. The coil 96 has a tail 128 configured to resist excessive penetration of the device into the subject tissue so that the overall depth that the device is implanted in the tissue is controlled. The tail 128 may be configured in a variety of forms. The example of a tail shown in FIG. 8 comprises a single broad coil joined to the main body 125 of the device by an extension neck 127, which may be a continuation of the most proximal coil 116. When the device is implanted in tissue, the broad coil of the tail is positioned to be flush with the surface of the tissue. The broad coil tail distributes the migratory forces experienced by the device over a broad area of tissue surface. The tail resists penetration of tissue surface thereby preventing migration of the device further into the tissue. Additionally, filament 126 from which the coil is formed may be a solid material or may, itself, be a coil spring structure having a plurality of openings between turns of the coil, which serve to permit herniation of surrounding tissue into the coil for anchoring capability. The broad coil tail 128 has a proximal end 130 which is preferably joined to the broad coil to maintain the coil circular shape. The proximal end 130 can be joined to the broad coil 128 by a variety of means such as welding as is shown by weld 132.

Paragraph beginning at line 26 of page 11 has been amended as follows:

FIG. 9 shows an alternative embodiment of joining the proximal end 130 to the broad coil tail 128. The alternative embodiment comprises wrapping the portion of the filament adjacent the proximal end 130 around the broad coil tail 128 in several turns 134. FIG. 10 shows another alternative embodiment useful for joining the proximal end 130 of the coil 96 to the broad coil tail 128. The alternative embodiment utilizes a malleable sleeve 136 to encompass both a portion of the broad coil tail 128 and the distal end of the coil 130. The malleable sleeve is then crimped to mechanically grasp the distal end 130 and broad coil and join them so that the circular shape of the broad coil tail 128 is maintained.

Paragraph beginning at line 3 of page 12 has been amended as follows:

The broad coil tail 128 need not be a circular shape but may have a variety of broad shapes capable of serving to disperse migratory forces over a broad surface area of tissue when the device is implanted. FIG. 11 shows a possible non-circular shape for the broad coil comprising a star shaped 137. FIG. 12 shows yet another alternative embodiment for the shape of the broad coil tail 128. In FIG. 12 a somewhat oval broad coil 138 is shown. Additionally, the broad coil 138 has plurality of distally projecting protrusions 139, which may increase the grasp of the coil into the tissue to prevent migration.

Paragraph beginning at line 1 of page 14 has been amended as follows:

An alternative method of anchoring the device comprises applying a surgical adhesive to the site of the implant such that adhesive is joined to the implant device and to surrounding tissue so that it is adhered. As described previously, one method of applying the surgical adhesive may comprise applying it directly at the surgical site or manually or delivering a quantity of surgical adhesive through the obturator delivery device directly to the cavity 14 created in the tissue by the device.